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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
O'DELL, DAVID K	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
01/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,600	AYSCOUGH ET AL.	
	Examiner	Art Unit	
	David K. O'Dell	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *14-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This application is a 371 of PCT/GB03/01541 filed 04/09/2003 which claims priority to UNITED KINGDOM application 0208579.3 filed 04/13/2002.

2. Claims 1-18 are pending. Claims 14-16 are withdrawn from consideration.

Election/Restrictions

Response to Restriction/Election

3. Applicant's election of group I and the species Example 1 in the reply filed on November 4, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP §818.03(a)). This requirement is made FINAL. This application contains claims drawn to a nonelected invention with traverse. A complete reply to this action must include a cancellation of nonelected claims or other appropriate action.

Under examination:

.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-13, 17-18 drawn to compounds and compositions. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Objections

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Since antibacterial agents are of a very diverse nature structurally, it is suggested that some description of the structure of the

compounds be given. An acceptable title might be: Piperidinyl N-Formyl Hydroxylamine Anti-Bacterials.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-6, 9-13, 17-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims refer to the variable R3 as "the side chain of a natural or non-natural alpha amino acid", however the specification does not fully elaborate as the full scope of this description as it is simply defined as Rx (pg. 12 of the specification), and then some examples are given. Describing the compound as natural or unnatural does nothing to remedy the situation. The term natural, could mean one of the twenty most common amino acids, or one of the vast number of other amino acids, for example pyrrolysine is a natural amino acid, as is selenocysteine as well as other "natural" amino acids that are found in nature and are not of these twenty. A complete list is not known and many may be waiting to be discovered. The term unnatural is equally deficient. The use of "for example" without fully delineating the identity of these groups renders the claim indefinite.

6. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is drawn to compounds "specifically named and/or exemplified herein or is the hydroxymate". It is improper to refer to the specification in this manner. The claims should be self-contained and self-referential. See *Ex Parte Fressola* 27 USPQ2d 1608:

"The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. Claims in utility applications [1] that define the invention entirely by reference to the specification and/or drawings, so-called "omnibus" or "formal" claims, while perhaps once accepted in American patent practice, are properly rejected under Section 112 Para. 2 as failing to particularly point out and distinctly claim the invention. See MPEP Section 706.03(h) (5th ed., rev. 14, Nov. 1992); Landis, Mechanics of Patent Claim Drafting, Section 2 (1974). This analysis is limited to claims in utility applications. Plant patent claims are defined "in formal terms to the plant shown and described." Claims in design patents are recited in formal terms to the ornamental design "as shown" or, where there is a properly included special description of the design, the ornamental design "as shown and described." MPEP Section 1503.01…….The general rule is that the claims should be self-contained; that is, they should not expressly rely upon the description or drawing to give them meaning. . . . The terms "substantially as described" and the like, once much used in claims (GLASCOCK 1943 Section 5640) are now rarely seen. The Office disregards them in interpreting claims. . . . Claims consisting only in a reference to the disclosure, as "The features of novelty herein disclosed," are not allowed except in design cases……A claim which refers to the specification defeats the purpose of a claim."

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

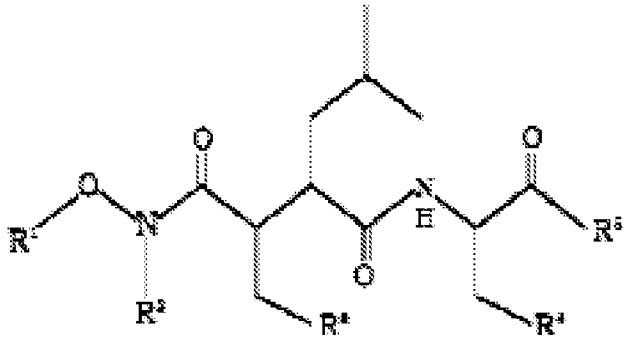
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-13, 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henmi et. al. JP 08053403 A, in view of Fujimoto WO 2002072577 A2.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

A) Determining the scope and contents of the prior art.
B) Ascertaining the differences between the prior art and the claims at issue.

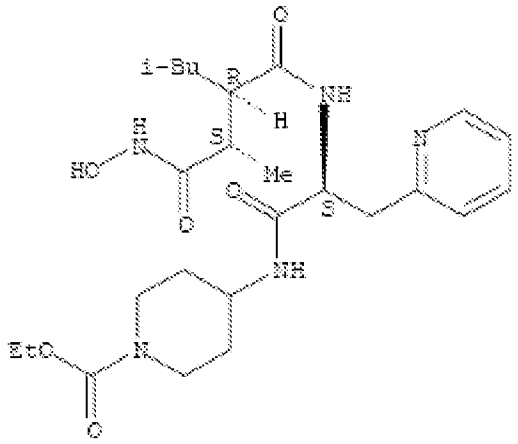
Henmi et. al. teach the following genus of compounds:



(I)

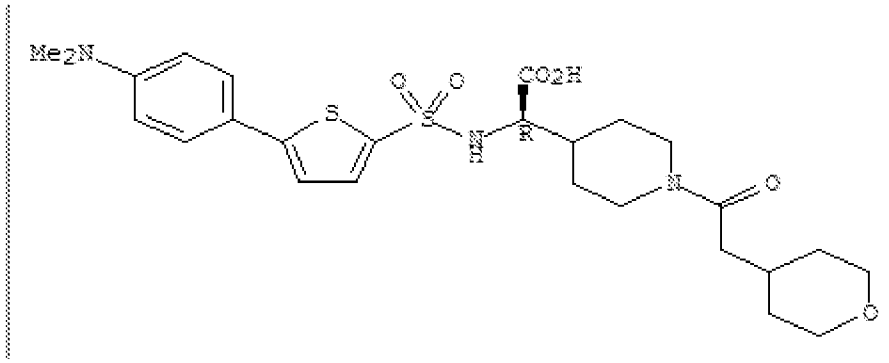
"This compound is expressed by formula I (R1 is H or a hydroxy- protecting group; R2 is H, a lower alkyl or an amino-protecting group; R3 is H or 2-thienylthuo; R4 is 2-pyridyl or its N-oxide, 4-pyridyl, phenyl or 4- methoxyphenyl; R5 is hydroxy, a lower alkoxy or amino having a substituent group, with the proviso that R4 is 2-pyridyl or its N-oxide or 4-pyridyl when R1 and R2 are each H) or its pharmaceutically permissible salt, e.g. [(2R,3 S)-4-(hydroxylamino)-2-isobutyl-3-(2-thienylthiomethyl)succinyl]-L-2-pyridylalanine- N-methylamide. The compound is obtained by reacting a compound of formula II or its reactive derivative or salt with a compound of formula III or its reactive derivative or salt."

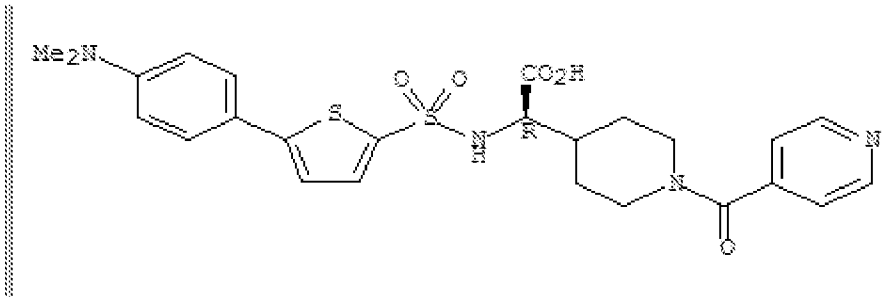
A particular species is the compounds where R5 is or amino having a 4-piperidinyl moiety with an acyl group as shown below:

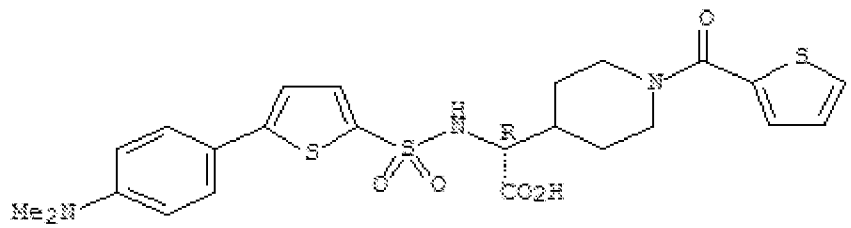


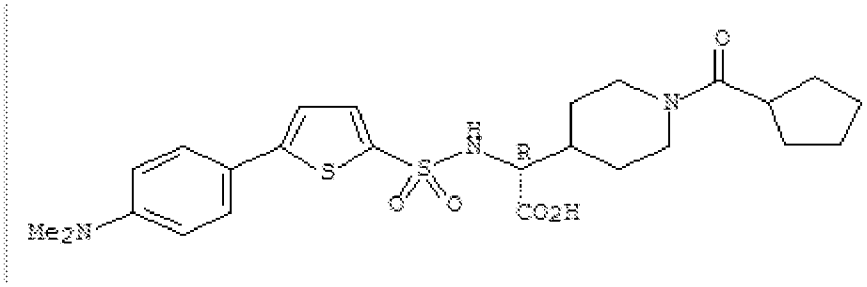
Fujimoto, WO 2002072577 A2 teaches collagenase inhibitors bearing piperidinyl groups with a variety of acyl substituents which are exactly those of the instant claims, (i.e. C=OR_5 of claim 1).

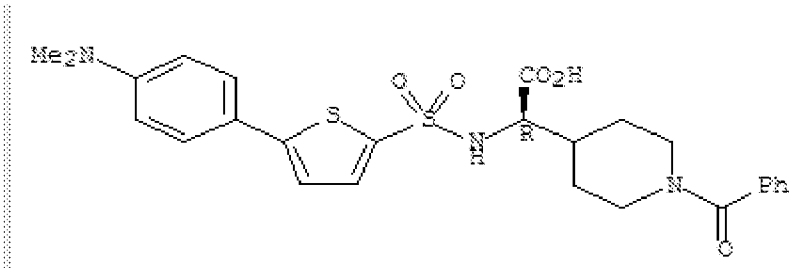
These compounds are shown below:

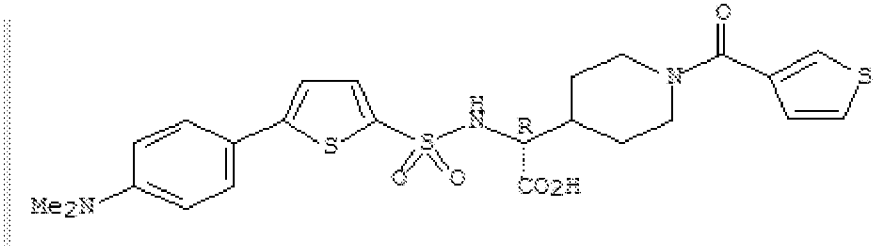




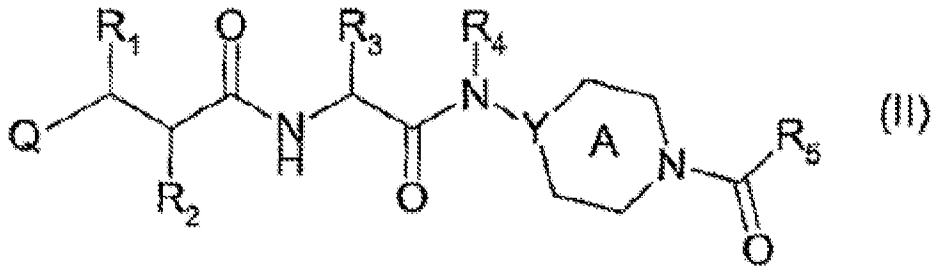








At least where R3 of the instant claims is a methyl pyridyl (i.e. the R4 of Henmi), the only difference is the selection of the acyl group (i.e. R5 of the instant claims)



(II)

C) Resolving the level of ordinary skill in the pertinent art.

The level of ordinary skill is high. Someone preparing these compounds would be trained in organic and medicinal chemistry and would recognize the very close structural similarity and would expect them to have similar properties. It would be routine for a chemist to prepare analogs differing only in the replacement of acyl groups on a piperidine as shown by the teaching of Fujimoto, such reactions could be readily accomplished by reaction with an acyl chloride..

D) Considering objective evidence present in the application indicating obviousness or nonobviousness.

The compounds of the instant case are analogs of old compounds. One of ordinary skill would be motivated to make the compounds of the invention because he would expect the compounds to have similar properties and increased potency and selectivity. *In re Grabiak* 226 USPQ 870, "[w]hen chemical compounds have "very close" structural similarities and similar utilities, without more a *prima facie* case may be made", *In re Deuel* 34 USPQ2d 1210, "a known compound may suggest its **analogs** or isomers, either geometric isomers (*cis* v. *trans*) or position isomers (emphasis added) (*e.g. ortho v. para*)". Compounds that are active as collagenase inhibitors may be useful for treating diseases. The secondary references show the routine nature of substitution of piperidine moiety and teach exactly the same acyl groups even

in this very narrow field, and without a showing of unexpected results a *prima facie* case of obviousness is appropriate.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-13, 16, 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain compounds it does not reasonably provide enablement for the scope of compounds bearing the extensive list of substituents. The compounds that are enabled are as follows:

R_1 is H.

R_2 as defined in claim 4 or claim 5.

R_3 as defined in claims 7-8.

R_4 is methyl.

R_5 where the Z group is defined as in claim 18.

Y is CH.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to the following:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(A) The breadth of the claims: The claims are very broad encompassing all heterocycles, carbocycles and other groups bearing multiple substitutions, some of which are of undefined scope (i.e. the variable R3 as "the side chain of a natural or non-natural alpha amino acid") **(B) The nature of the invention:** This is a chemical invention requiring the synthesis of compounds and such compounds should have activity as anti-bacterials. **(D) The level of one of ordinary skill**: One of ordinary skill is a practicing organic/medicinal chemist. **(C) The state of the prior art: (E) The level of predictability in the art: (F) The amount of direction provided by the inventor, (G) The existence of working examples, and (H) The quantity of experimentation needed to make or use the invention:** Each one of the factors (**C**, **E-H**) will be discussed in light of the scientific literature when such a factor is being directly pointed to a large capital letter referring to the aforementioned Wands factor will be placed directly after such a remark or explication. The examiner will first consider the Markush structure I of claim 1, and discuss the limitations inherent to the chemistry required to prepare the compounds. At least for the examples given (Examples 1-56) of the specification, only one synthetic route was given on pages 22-27, where a single protected N-methyl α-amino acid (N-methyl-tert-leucine) was coupled to a Boc-protected piperidine (Step 3). This compound was then reacted with a very specialized β-N-formylhydroxyamino acid (step 4). The only example of R_3 given is t-butyl, and

that of R_2 is CH_2cyclopentyl, Y is CH, in all of the working examples 1-56, and while the scheme is certainly applicable to other derivatives, the claims are so broad that a research project would need to be conducted to prepare the vast number of non-disclosed and non-described protected N-methyl α-amino acid specialized β-N-formylhydroxyamino acid. The synthesis and production of new alpha and beta amino acids is in itself a field of inquiry and the chemistry disclosed here does not mark a trail to the scope of the claims. See Aurelio et. al. "Synthetic Preparation of N-Methyl-α-amino Acids" Chemical Reviews, 2004, 104, 5823-5846, where the authors come to the conclusion:

"It is obvious from the material reviewed that the methods for installing the N-methyl moiety in the full range of amino acids are challenging…….. At the present time synthetic routes to all natural NMAs have been described; however, extensive use of NMAs as building blocks for modified peptides has not been developed because a range of protected NMAs are not available. If such building blocks were more widely commercially available, there would be an exponential growth in the use of these compounds in peptide synthesis as well as in development of associated technologies including coupling reactions, ring formation, and side-chain manipulation." Pg 5845.

As per MPEP:

> A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court in In re Ghiron, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. In re Howarth, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

According to the U.S. Court of Customs and Patent Appeals in *In re Argoudelis, De Boer, Eble, and Herr* 168 USPQ 99 at 101, "[o]rdinarily no problem in this regard arises since the method of preparing almost all starting materials can be set forth in writing if the materials are not already known and available to the workers in the art, and when this is done the specification is enabling

to the public". *In re Argoudelis, De Boer, Eble, and Herr* 168 USPQ 99 at 104, "it is essential that there be no question that, *at the time an application for patent is filed,* (emphasis in original) the invention claimed therein is fully capable of being reduced to practice (i.e., that no technological problems, the resolution of which would require more than ordinary skill and reasonable time, remain in order to obtain an operative, useful embodiment)." That is not the situation here. Rather we find very little direction as to how the many required staring materials with these vast substituents are to be obtained. Where may the directions to prepare or buy them be found? **(F)**

In re Howarth, 210 USPQ 689, (claimed derivatives of clavulanic acid not enabled by specification lacking information of how prepare the clavulanic acid or directions to reference materials containing such information), *Ex parte Schwarze* 151 USPQ 426 (where starting material is not known to art as of date of filing application, there must be included a description of preparation thereof to enable one skilled in this art to carry out applicant's invention), *Ex parte Moersch* 104 USPQ 122 (claims to process for the production of (1)-y1-p-nitrophenyl-2-dichloracetamindo-propane-1,3-diol not enabled because of failure to describe source or method of obtaining starting compound; although starting compound is identified by means of appropriate name and by structural formula).

While these chemical limitations are significant, perhaps more significant are the limitations of activity as antibacterials. What are the important structural features for the claimed utility? It is clear from the data in the specification that the structural features of the compound are important for activity. All the compounds have R1 as H, R4 is Me, R3 is t-butyl and R2 as CH2-cyclopentyl.

(H) The medicinal chemistry of actinonin analogs bearing a very similar core is relatively well-developed and many limitations are well known in the art. It is sensitive to structural changes that may be relatively minor in the chemical sense see Davies et. al. "Structure–Activity Relationships of the Peptide Deformylase Inhibitor BB-3497: Modification of the Methylene Spacer and the P10 Side Chain" *Bioorganic & Medicinal Chemistry Letters* **2003**, *13*, 2709–2713. The core is described in the following way in Figure 1, shown below:

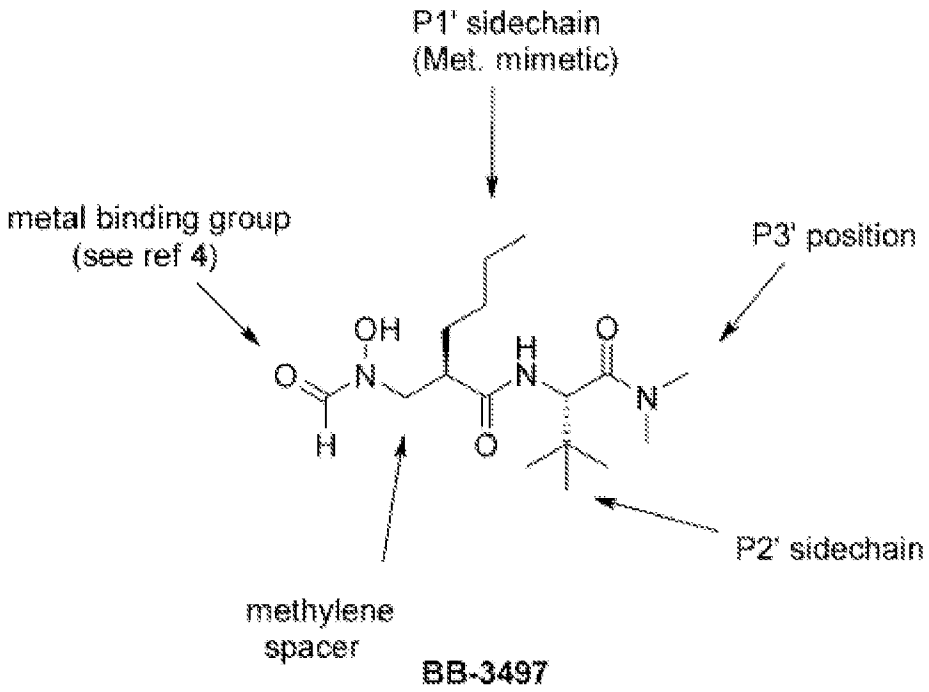


Figure 1. BB-3497 structure–activity relationships.

The P1 portion corresponds to the R_2 variable of the instant case, and the P2' side chain corresponds to the R_3 variable.

"**The rigid geometry around the metal binding group and the distance to the P10 pocket allows for little modification in this region of the inhibitor.** The activity of P10 analogues of BB-3497 against the PDF enzyme is consistent with a well defined hydrophobic S10 pocket. In correlation with the structural information obtained from X-ray data, this pocket is capable of accommodating small alkyl, cycloalkyl and benzylic groups. Variation in the length of the P10

alkyl chain (Table 2) (23a–23c, 23e–23h) revealed that n-butyl was optimal (BB-3497). However, the enzyme also accommodated a variety of other substituents. Branching of the alkyl chain (23i–23k), addition of a cycloalkyl substituent (23l–23n) and the presence of unsaturation or a sulfur atom(23–23s) in the P10 side chain all gave rise to potent PDF enzyme inhibitors. Incorporation of a benzylic group was acceptable (23t) but a substituent on the ring (23v) resulted in a 10-fold reduction in PDF inhibition. Introduction of a basic nitrogen (23w) and a directly linked aromatic group (23u) were detrimental to PDF inhibition."

See also Davies et. al. "Structure–Activity Relationships of the Peptide Deformylase Inhibitor BB-3497: Modification of the P20 and P30 Side Chains" *Bioorganic & Medicinal Chemistry Letters* 2003, 13, 2715–2718, where it is suggested that some variability at R_3 may not be detrimental to function:

"Modifications adjacent to the metal binding group and to the n-butyl substituent are limited due to the steric requirements for binding the active site metal and size of the hydrophobic P1' pocket.[10,11] Substituents that closely mimic the methionine of the substrate provide optimal PDF enzyme inhibition. In contrast, a range of substituents and functional groups are tolerated by PDF at the P2' and P3' positions. This observation is in line with crystallographic data that suggest these groups are largely exposed to solvent. These structural studies have also highlighted the importance of the backbone amide bonds for enzyme inhibition through hydrogen bonding interactions with the enzyme."

In this case these compounds bear a remarkable structural resemblance to one another, yet the claims are not commensurate in scope. The factors outlined in *In Re Wands* mentioned above apply here, and in particular As per the MPEP 2164.01 (a): "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." It is very clear that one could not make/use this very broad invention that has only four working examples in this unpredictable art without undue experimentation. **(C, E, F, G, H).**

8. Claims 1-13, 16, 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making solvates (or hydrates which are solvates) of the claimed compounds. The specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in scope with these claims. "The factors to be considered [in making an enablement rejection] have been summarized as a) the quantity of experimentation necessary, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. In the present case the important factors leading to a conclusion of undue experimentation are the absence of any working example of a formed solvate, the lack of predictability in the art, and the broad scope of the claims.

a) Determining if any particular substrate would form a solvate or hydrate would require synthesis of the substrate and subjecting it to recrystallization with a variety of solvents, temperatures, pressures, and humidity. The experimentation is potentially open-ended. b) The direction concerning the hydrates is not found in the specification. c) There is no working example of any hydrate or solvate formed. The claims are drawn to solvates, yet the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed

compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here. There is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

d) The nature of the invention is chemical synthesis, which involves chemical reactions. e) g) Chemical reactions are well-known to be unpredictable, *In re Marzocchi*, 169 USPQ 367, *In re Fisher*, 166 USPQ 18. The state of the solvate art is that is not predictable whether solvates will form or what their composition will be. In the language of the physical chemist, a solvate of organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). West, Anthony R., "Solid State Chemistry and its Applications, Wiley, New York, 1988, pages 358 & 365. The solvent molecule is a species introduced into the crystal and no part of the organic host molecule is left out or replaced. In the first paragraph on page 365, West (Solid State Chemistry) says, "it is not usually possible to predict whether solid solutions will form, or if they do form what is their compositional extent". Thus, in the absence of experimentation one cannot predict if a particular solvent will solvate any particular crystal. One cannot predict the stoichiometery of the formed solvate, i.e. if one, two, or a half a molecule of solvent added per molecule of host. In the same paragraph on page 365 West (Solid State Chemistry) explains that it is possible to make meta-stable non-equilibrium solvates, further clouding what Applicants mean by the word solvate. Compared with polymorphs, there is an additional degree of freedom to solvates, which means a different solvent

or even the moisture of the air that might change the stabile region of the solvate. h) The breadth of the claims includes all of the hundreds of thousands of compounds of formula I as well as the presently unknown list of solvents embraced by the term "solvate". Thus, the scope is broad.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell whose telephone number is (571)272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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D.K.O.

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